

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/758,365	KARAHALIOS, DEAN G.	
	Examiner Annette R. Reimers	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to correspondence filled on 12/20/06 and phone interview of 2/9/07.
2.  The allowed claim(s) is/are 1,3-18 and 20-24.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All b)  Some\* c)  None of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

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|---|--|
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
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EDUARDO J. ROBERT  
SUPERVISORY PATENT EXAMINER

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dustin Johnson, applicant's representative, on Friday, February 9, 2007.

The application has been amended as follows:

In the Claims:

In claim 1, lines 8-9, after "axial direction," delete "the tubular body and the side walls of the pair of cleat assemblies being free of interfacing threads."

In claim 1, line 8, after "axial direction," add -- wherein prior to interposition between the two vertebral endplates, the tubular body is slidably passed through the hollow bores in each of the cleat assemblies and wherein the spikes on each outer end wall are directed away from each other and extend toward opposite ends of the tubular body without extending past the opposite ends of the tubular body. --

Claim 2 has been cancelled.

In claim 12, lines 8-9, after "axial direction," delete "the biologic strut and the sidewall of the pair of cleat assemblies being free of interfacing threads."

In claim 12, line 8, after "axial direction," add -- wherein prior to interposition between the two vertebral endplates, the biologic strut is slidably passed through the hollow bores in each of the cleat assemblies and wherein the spikes on each outer end

Art Unit: 3733

wall are directed away from each other and extend toward opposite ends of the biologic strut without extending past the opposite ends of the biologic strut. --

In claim 15, lines 13-14, after "second cleat assembly," delete "the tubular body and the first and second side walls of the first and second cleat assemblies being free of interfacing threads."

In claim 15, line 13, after "second cleat assembly," add -- wherein the first cleat assembly is slidably passed over the first opposite end and the second cleat assembly is slidably passed over the second opposite end with the first spiked end wall directed toward the first opposite end and the second spiked end wall directed toward the second opposite end and wherein the spiked end walls do not extend beyond the first and second opposite ends. --

Claim 19 has been cancelled.

In the Specification:

In paragraph 0017, line 5, "tubular body 24" has been changed to -- tubular body 22 --.

### **Reasons for Allowance**

The following is an examiner's statement of reasons for allowance:

The claims in the instant application have not been rejected using prior art because no references, or reasonable combination thereof, could be found which disclose, or suggest an implant having a tubular body having opposite ends and sized to fit between two vertebral endplates and a pair of cleat assemblies, each cleat assembly

Art Unit: 3733

comprising an outer end wall and a side wall which defines a hollow bore, wherein one or more spikes extend from each outer end wall, wherein prior to interposition between the two vertebral endplates, the tubular body is slidably passed through the hollow bores in each of the cleat assemblies and wherein the spikes on each outer end wall are directed away from each other and extend toward opposite ends of the tubular body without extending past the opposite ends of the tubular body, as set forth in claim 1.

The claims in the instant application have not been rejected using prior art because no references, or reasonable combination thereof, could be found which disclose, or suggest a biologic strut having opposite ends and sized to fit between two vertebral endplates and a pair of cleat assemblies, each cleat assembly comprising an outer end wall and a side wall which defines a hollow bore, wherein one or more spikes extend from each outer end wall, wherein prior to interposition between the two vertebral endplates, the biologic strut is slidably passed through the hollow bores in each of the cleat assemblies and wherein the spikes on each outer end wall are directed away from each other and extend toward opposite ends of the biologic strut without extending past the opposite ends of the biologic strut, as set forth in claim 12.

The claims in the instant application have not been rejected using prior art because no references, or reasonable combination thereof, could be found which disclose, or suggest an implant comprising a tubular body having a first opposite end and a second opposite end, a first cleat assembly comprising a first spiked end wall and a second cleat assembly comprising a second spiked end wall, wherein the first cleat

Art Unit: 3733

assembly is slidably passed over the first opposite end and the second cleat assembly is slidably passed over the second opposite end with the first spiked end wall directed toward the first opposite end and the second spiked end wall directed toward the second opposite end and wherein the spiked end walls do not extend beyond the first and second opposite ends, as set forth in claim 15.

The claims in the instant application have not been rejected using prior art because no references, or reasonable combination thereof, could be found which disclose, or suggest the method steps of interposing a distracting device between the cleat assemblies and applying a distraction force with the distracting device to move at least one of the cleat assemblies into engagement with at least one of the vertebral endplates, as set forth in claim 21.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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